

Remarks

Upon entry of the foregoing amendment, claims 84-131 are pending in the application, with claims 84, 126, and 127 being the independent claims. Claims 109 and 112 are sought to be amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Support for the amendments to claims 109 and 112 is found throughout the specification and claims as originally filed.

Reply to Restriction Requirement and Election of Species

In reply to the Office Action dated **April 28, 2004**, requesting an election of one group of claims to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the claims of Group I. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to pursue the nonelected claims in one or more divisional applications.

This election is made **with** traverse.

With respect to the Examiner's division of the claims into five groups and the reasons stated therefor, Applicants respectfully traverse. Each of the groups is related. For example, Groups I and V¹ are related as between a method of selecting and/or producing polynucleotides which encode an antigen-specific immunoglobulin molecule (Group I) and a kit for selecting antigen-specific immunoglobulins from libraries of

¹ Applicants believe that, although this was labeled as Group "II" in the Office Action dated April 28, 2004, it should have been labeled as Group "V."

polynucleotides (Group V). Groups I and V are related to Group II as between a method, and an immunoglobulin produced by that method. Likewise, Groups II and III are related as between an immunoglobulin produced by a method of selecting polynucleotides which encode an antigen-specific immunoglobulin (Group II) and a composition comprising an antibody produced by a method of selecting polynucleotides which encode an antigen-specific immunoglobulin and a pharmaceutically acceptable carrier (Group III). Groups I and V are related to Group IV as between a method of selecting and/or producing polynucleotides which encode an antigen-specific immunoglobulin molecule and a host cell which expresses an antigen-specific immunoglobulin.

Even assuming, *arguendo*, that Groups I-V represent distinct or independent inventions, Applicants submit that to search and examine the subject matter of these Groups together would not be a serious burden on the Examiner. In particular, any art related to a method of selecting from libraries of polynucleotides polynucleotides which encode an antigen-specific immunoglobulin molecule is very likely to overlap substantially with art related to a kit for selecting antigen-specific immunoglobulins from libraries of polynucleotides and with art related to a host cell which expresses an antigen-specific immunoglobulin. Similarly, art related to an antibody produced by a method of selecting polynucleotides which encode an antigen-specific immunoglobulin is very likely to substantially overlap with art related to a composition comprising an antibody produced by a method of selecting polynucleotides which encode an antigen-specific immunoglobulin and a pharmaceutically acceptable carrier. Accordingly, it would not be an undue burden for the Examiner to search, at a minimum, Groups I, IV, and V

together, and Groups II and III together. The M.P.E.P. § 803 (Eighth Edition, Rev. August, 2001) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of the M.P.E.P. § 803, Applicants respectfully request that all claims be searched and examined in the subject application. Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

The Examiner has also required a large number of species elections. Applicants' provisional elections are listed below, along with a listing of each of the claims believed to read on each of the provisionally-elected species.

These elections are made **with** traverse.

Subgroup 1. The Examiner has required an election of species among host cells. Applicants hereby provisionally elect to prosecute the species comprising a HeLa cell which is permissive for the production of infectious viral particles. Claims 84-131 are generic to the provisionally elected species.

Subgroup 2. The Examiner has required an election of species among a second library of polynucleotides' ability to infect. Applicants hereby provisionally elect to prosecute the species comprising a second library that is capable of producing infectious

particles. Claims 84, 88, 96, 97, 100-124, and 126-131 are generic to the provisionally elected species. Claims 89-95, 99, and 125 specifically read on the provisionally elected species.

Subgroup 3. The Examiner has required an election of species among repeating steps (f)-(j). In order to be fully responsive, Applicants hereby provisionally elect to prosecute the species comprising one repetition of steps (f)-(j). Claims 84-131 are generic to the provisionally elected species. However, Applicants respectfully assert that the number of repetitions of steps for enrichment of polynucleotides does not represent a separate species to be elected. Searching claims that involve repeating the same steps multiple times will not be burdensome to the Examiner, and, in fact, should involve no additional effort at all.

Subgroup 4. The Examiner has required an election of species among repeating steps (p)-(t). In order to be fully responsive, Applicants hereby provisionally elect to prosecute the species comprising one repetition of steps (p)-(t). Claims 84-131 are generic to the provisionally elected species. However, Applicants respectfully assert that the number of repetitions of steps for enrichment of polynucleotides does not represent a separate species to be elected. Searching claims that involve multiple repetitions of the same steps will not be burdensome to the Examiner, and, in fact, should involve no additional effort at all.

Subgroup 5. The Examiner has required an election of species among immunoglobulins. Applicants hereby provisionally elect to prosecute the species

comprising a secreted form of human IgG. Claims 84-131 are generic to the provisionally elected species.

Subgroup 6. The Examiner has required an election of species among the first and second library construction. Applicants hereby provisionally elect to prosecute the species comprising a vaccinia virus which is not attenuated and is not deficient in D4R synthesis for both first and second library construction. Claims 84-104 and 107-131 are generic to the provisionally elected species.

Subgroup 7. The Examiner has required an election of species among promoters. Applicants hereby provisionally elect to prosecute the species comprising a T7 phage promoter which is constitutive and is not a synthetic early/late promoter. Claims 84-99 and 103-131 are generic to the provisionally elected species.

Subgroup 8. The Examiner has required an election of species among transcriptional control regions. Applicants hereby provisionally elect to prosecute the species comprising a promoter that is under the control of T7 polymerase. Claims 84-99 and 105-131 are generic to the provisionally elected species. Claim 103 specifically reads on the provisionally elected species.

Subgroup 9. The Examiner has required an election of species among vaccinia virus genomes. Applicants hereby provisionally elect to prosecute the species comprising v7.5/tk virus genome for both the first and second libraries. Claims 84-131 are generic to the provisionally elected species.

Subgroup 10. The Examiner has required an election of species among viral fragment generation. Under this subgroup, the Examiner appears to require Applicants to elect a single unique restriction site that would generate a viral fragment. In order to be fully responsive, Applicants would provisionally elect to prosecute the species comprising a NotI restriction site. Claims 84-131 are generic to the provisionally elected species. However, under the present invention, there must be at least two unique restriction sites in order to generate the viral fragment.

Subgroup 11. The Examiner has required an election of species among repeating steps (a)-(d). In order to be fully responsive, Applicants hereby provisionally elect to prosecute the species comprising one repetition of steps (a)-(d). Claims 84-131 are generic to the provisionally elected species. However, Applicants respectfully assert that the number of repetitions of steps for enrichment of polynucleotides does not represent a separate species to be elected. Searching claims that involve multiple repetitions of the same steps will not be burdensome to the Examiner, and, in fact, should involve no additional effort at all.

Subgroup 12. The Examiner has required an election of species among repeating steps (a)-(d). In order to be fully responsive, Applicants hereby provisionally elect to prosecute the species comprising one repetition of steps (a)-(d). Claims 84-131 are generic to the provisionally elected species. However, Applicants respectfully assert that the number of repetitions of steps for enrichment of polynucleotides does not represent a separate species to be elected. Searching claims that involve multiple repetitions of the

same steps will not be burdensome to the Examiner, and, in fact, should involve no additional effort at all.

Subgroup 13. The Examiner has required an election of species among detection methods. Applicants hereby provisionally elect to prosecute the species comprising detection by ELISA. Claims 84-120 and 123-131 are generic to the provisionally elected species. Claims 121 and 122 specifically recite the provisionally elected species.

Subgroup 14. The Examiner has required an election of species among transfer plasmids. Under this subgroup, the Examiner appears to require Applicants to elect a type of transfer plasmid. In order to be fully responsive, Applicants would provisionally elect to prosecute the species comprising pVHE, which encodes an immunoglobulin heavy chain, which has a vaccinia virus promoter, and which contains flanking regions capable of homologous recombination with the region of the vaccinia virus genome containing the thymidine kinase gene. Claims 84-131 are generic to the provisionally elected species. However, the claims recite complete, bivalent immunoglobulins, or antigen-specific fragments thereof, which comprise heavy *and* light chains. Accordingly, libraries of polynucleotides which are constructed by a method comprising providing a population of transfer plasmids would require both transfer plasmids that encode immunoglobulin heavy chains, or a fragment thereof and transfer plasmids that encode immunoglobulin light chains, or a fragment thereof.

Subgroup 15. The Examiner has required an election of species among signal peptides. Applicants hereby provisionally elect to prosecute the species comprising an

immunoglobulin heavy chain signal peptide corresponding to amino acids -19 to -3 of IgM heavy chain. Claims 84-131 are generic to the provisionally elected species.

Applicants respectfully traverse and request the withdrawal of the requirement for election of species. As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – §806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the groups listed by the Examiner represent patentably distinct species, restriction remains improper unless it can be shown that the search and examination of the listed groups would entail a "serious burden." See M.P.E.P. § 803. In the present situation, no such showing has been made. For example, although the Examiner has asserted that embodiments referring to immunoglobulins are distinct species, Applicants submit that a search of IgG as an immunoglobulin would provide useful information regarding other types of immunoglobulin, such as IgM. Similarly, the search and examination of all of the claims of Group I would not entail a serious burden.

Applicants assert the right to claim additional embodiments in the event that a generic claim thereto is found to be allowable in accordance with 37 C.F.R. § 1.141(a).

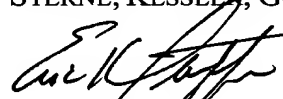
Reconsideration and withdrawal of the Requirement for Election of species, and consideration and allowance of all pending claims, are respectfully requested.

Summary

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Eric K. Steff
Attorney for Applicants
Registration No. 36,688

Date: May 28, 2004

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
268154_1.DOC